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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/489,846	01/24/2000	Hideya Takeo	Q56532	6337

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EXAMINER
MILLER, RYAN J

ART UNIT	PAPER NUMBER
2621	

DATE MAILED: 03/12/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/489,846	TAKEO, HIDEYA	
	Examiner	Art Unit	
	Ryan J. Miller	2621	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-13 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-13 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on 24 January 2000 is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Response to Amendment

1. The amendment received on January 14, 2003 has been entered. Claims 1-13 are pending in this application. In response, applicant's arguments with respect to claims 1-8 have been considered but are moot in view of the new ground(s) of rejection necessitated by the applicant's amendments to the claims.

Claim Rejections - 35 USC § 112

2. Claims 5-8 define applicant's invention in a "means plus function" format, each reciting a "mean for" followed by functional language, and not limited by structure. Thus, "means plus function" is automatically invoked (*In re Donaldson Co., 16 F.3d 1189, 29 USPQ2d 1845 (Fed. Cir. 1994); Refer to MPEP 2181*). However, in order to invoke mean plus function, the 35 U.S.C. 112, second paragraph requirements must be met (MPEP 2181, PROCEDURES FOR DETERMINING WHETHER THE WRITTEN DESCRIPTION ADEQUATELY DESCRIBES THE CORRESPONDING STRUCTURE, MATERIAL, OR ACTS NECESSARY TO SUPPORT A CLAIM LIMITATION WHICH INVOKES 35 U.S.C. 112, SIXTH PARAGRAPH). The MPEP (2181) states, and supports with the applicable law, the following:

> "If a claim limitation invokes 35 U.S.C. 112, sixth paragraph, it must be interpreted to cover the corresponding structure, materials, or acts in the specification and "equivalents thereof." See 35 U.S.C. 112, sixth paragraph. See also B. Braun Medical, Inc. v. Abbott Lab., 124 F.3d 1419, 1424, 43 USPQ2d 1896, 1899 (Fed. Cir. 1997). If the written description fails to set forth the supporting structure, material or acts corresponding to the means- (or step-) plus-function, the claim may not meet the requirement of 35 U.S.C. 112, second paragraph:

> Although [35 U.S.C. 112, sixth paragraph] statutorily provides that one may use means-plus-function language in a claim, one is still subject to the requirement that a claim particularly point out and distinctly claim' the invention. Therefore, if one employs means-plus-function language in a claim, one must set forth in the specification an adequate disclosure showing what is meant by that language. If an applicant fails to set forth an adequate disclosure, the applicant has in effect failed to particularly point out and distinctly claim the invention as required by [35 U.S.C. 112, second paragraph].
>
> See Donaldson, 16 F.3d at 1195, 29 USPQ2d at 1850; see also B. Braun Medical, 124 F.3d at 1425, 43 USPQ2d at 1900; and In re Dossel, 115 F.3d 942, 946, 42 USPQ2d 1881, 1884-85 (Fed. Cir. 1997)."

and

> "Therefore, a means-(or step-) plus-function claim limitation satisfies 35 U.S.C. 112, second paragraph if: (A) the written description links or associates particular structure, materials, or acts to the function recited in a means- (or step-) plus-function claim limitation; or (B) it is clear based on the facts of the application that one skilled in the art would have known what structure, materials, or acts perform the function recited in a
> means- (or step-) plus-function limitation."

Upon reviewing applicant's original disclosure (i.e., specification, claims and drawings), it is the examiner's conclusion that the written description does not link or associate particular structure to the function recited in the means-plus-function claim limitations, and it is not clear based on the facts of the application that one skilled in the art would have known what structure or materials perform the function recited in a means-plus-function limitation". For example, claim 5 recites, "a means relating a result of said detection processing to a corrected detection processing result, for each of a plurality of items of said image information". Figures 1 and 9 depict an overview of an embodiment of the claimed system. Nowhere in these two figures is a relating means found. Furthermore, this relating means is not clearly discussed in the disclosure. How is this relating means performing a relation between the result of the detection processing

and a corrected detection processing result? Thus, the 35 U.S.C. 112, second paragraph requirements have not been met for the means-plus-function language. The claims will be interpreted as broadly as if mean-plus-function were not invoked, as this is how broad the apparatus is disclosed.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claims 1-3 are rejected under 35 U.S.C. 102(e) as being anticipated by Rogers et al. (U.S. Patent Application Publication No. US 2002/0081006 A1).

As applied to claim 1, Rogers et al. discloses an abnormal pattern detection processing method comprising: detecting an abnormal pattern in an image, based on inputted image information (see paragraph [0042]: The reference describes detecting microcalcifications (i.e. abnormal pattern) in a digital mammogram.); processing the detected abnormal pattern (see paragraph [0042]: The reference describes filtering the image to reduce noise and then filtering the image using an optimized difference of Gaussians (DoG) filter to enhance the microcalcifications. These first two steps correspond to determining a second set of suspicious detections, S2, described in paragraph [0014].); correcting the processed abnormal pattern, for each of a plurality of items of the inputted image information (see paragraph [0014]: The reference describes that a radiologist examines the suspicious detections of the CAD system and

either rejects or accepts them (i.e. correcting the processed abnormal pattern).); relating a result of the processed abnormal pattern to a result of the corrected abnormal pattern, for each of the plurality of items of the inputted image information (see paragraph [0014]: The reference describes that the CAD system outputs, S2, are incorporated with the radiologist's analysis to optimize the overall sensitivity of detecting true positives (i.e. relating a result of the processed abnormal pattern to a result of the corrected abnormal pattern).); and storing the plurality of processed abnormal pattern results and the plurality of corrected abnormal pattern results (see paragraph [0046]: The reference describes that the digital images are stored on a computer-readable storage medium.).

As applied to claim 2, Rogers et al. discloses that quantitative evaluation of the detection processing is performed, on the basis of the stored plurality of processed abnormal pattern results and the stored plurality of corrected abnormal pattern results (see paragraphs [0014] and [0137]: The quantitative evaluation the relating described above. The CAD system outputs are incorporated with the radiologist's analysis to optimize the overall sensitivity of detecting true positives. Further quantitative evaluations such as specificity and the positive predictive value are also determined from this data.).

As applied to claim 3, Rogers et al. discloses an abnormal pattern detection processing method comprising: detecting an abnormal pattern in an image, based on inputted image information (As described in the rejection of claim 1.); processing the detected abnormal pattern (As described in the rejection of claim 1.); performing a pattern reading assessment using the image information (see paragraph [0014]: The reference describes that a radiologist examines the suspicious detections of the CAD system and either rejects or accepts them, thus forming a third

set of suspicious detections S3.); performing a pathologic assessment of the abnormal pattern (see paragraph [0014]: The reference describes that a radiologist reviews the image and reports a set of suspicious regions, S1 (i.e. a pathologic assessment of the abnormal pattern).); relating a result of the detected abnormal pattern processing and a result of the pattern reading assessment to a result of the pathologic assessment, for each of a plurality of items of the inputted image information (As described in the rejection of claim 1.); and storing the plurality of processed detected abnormal pattern results, the plurality of pattern reading assessment results and the plurality of pathologic assessment results (As described in the rejection of claim 1.).

As applied to claim 4, Rogers et al. discloses that a quantitative evaluation of the pattern reading assessment is performed, on the basis of the stored plurality of pattern reading assessment results and the stored plurality of pathologic assessment results (As described in the rejection of claim 2).

As applied to claim 5, Rogers et al. discloses an abnormal pattern detection processing system, which detects (see Fig. 1: Block 300 which represents detecting clustered microcalcifications.) and processes an abnormal pattern (see Fig. 1: Block 600 which represents processing the results) in an image represented by image information on the basis of inputted image information, comprising: a means relating a result of the detection processing to a corrected detection processing result, for each of a plurality of items of image information (see Fig. 31: The combination of blocks 50 through 70 depict that the CAD system outputs, S2, are incorporated with the radiologist's analysis to optimize the overall sensitivity of detecting true positives.); and memory means storing the plurality of detection processing results and the

plurality of corrected detection processing results (see paragraph [0046]: The reference describes the use of a 2 GB hard drive of a general-purpose computer for storing information).

As applied to claim 6, Rogers et al. discloses evaluator means for performing quantitative evaluation of the detection processing on the basis of the plurality of results of detection processing and corrected detection processing results stored in the memory means (This evaluation is the same evaluation as described in the rejection of claim 2. Since the reference describes a computerized system (see paragraph [0046]), then the computers processor acts as the evaluator means.)

As applied to claim 7, Rogers et al. discloses an abnormal pattern detection processing system, which detects and processes an abnormal pattern in an image represented by image information on the basis of inputted image information (As described in the rejection of claim 5 above.), comprising: a means relating a result of the detection processing and a result of a pattern reading assessment using the image information to a result of pathologic assessment concerning the abnormal pattern, for each of a plurality of items of the image information (As described in the rejection of claim 5 above); and memory means storing the plurality of detection processing results, the plurality of pattern reading assessment results and the plurality of pathologic assessment results (As described in the rejection of claim 5 above.).

As applied to claim 9, Rogers et al. discloses that the corrected abnormal pattern results comprise a determination of whether the processed abnormal pattern corresponds to at least one of a true positive, false positive, true negative and false negative (see paragraph [0137]: The reference describes the use of true positive, false positive, true negative and false negative to rate the detected clusters.).

As applied to claim 10, Rogers et al. discloses that quantitative evaluation comprises a ratio of a number of true results relative to a number of true and false results (see equations (11), (12), and (13): These equations represent sensitivity, specificity, and positive predictive value (PPV), respectively, which are all a ratio of a number of true results relative to a number of true and false results.

As applied to claim 11, Rogers et al. discloses that a sensitivity of the quantitative evaluation is determined by the ratio of true positives to a sum of true positives and false negatives (see equation (11), following paragraph [0133]).

As applied to claim 12, Rogers et al. discloses a specificity of the quantitative evaluation is determined by the ratio of true negatives to a sum of true negatives and false positives (see equation (12), following paragraph [0134]).

As applied to claim 13, Rogers et al. discloses a positive predictive value of the quantitative evaluation is determined by the ratio of true positives to a sum of true positives and false negatives (see equation (13), following paragraph [0138]).

Response to Arguments

5. Applicant's arguments filed on January 14, 2003 have been fully considered.

Drawing Objection

Summary of Argument: The drawing objection should be withdrawn in light of the amendment.

Examiner's Response: Examiner agrees. The objection has been withdrawn in light of the amendment to the specification.

Specification Objection

Summary of Argument: The specification objection should be withdrawn in light of the amendment.

Examiner's Response: Examiner agrees. The objection has been withdrawn in light of the amendment to the specification.

Rejection Under 35 U.S.C. 112, First Paragraph

Summary of Argument: Claims 5 and 7 have been amended to divide the claim elements more particularly, thereby overcoming the rejection.

Examiner's Response: Examiner agrees. The rejection has been withdrawn in light of the amendments to claims 5 and 7.

Rejection Under 35 U.S.C. 112, Second Paragraph

Summary of Argument: Claims 1-8 were amended to improve the structure and language used, as well as correcting antecedent basis problems. Therefore, the indefiniteness rejection of claims 1-8 is overcome.

Examiner's Response: Examiner agrees. The rejection has been withdrawn in light of the amendments to claims 1-8.

Prior Art Rejections

35 U.S.C. 102(e) rejections

Summary of Argument: Applicant believes that the anticipation rejection of claims 1-8 based on Evans (U.S. Patent No. 5,924,074 A) is without merit. Evans relates to an electronic medical records system in which various medical records are created and maintained. By contrast, the applicant's invention relates to a system and method for performing abnormal pattern detection processing of images. Therefore, Evans' system, which manipulates data after it has been collected, is quite different from the present invention.

Examiner's response: Examiner agrees; however, the applicant's arguments with respect to claims 1-8 are moot in view of the new ground(s) of rejection necessitated by the amendment to the claims. This rejection was presented in the preceding paragraph.

Conclusion

6. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Fields et al. (the paper titled "Clinical Evaluation of Computerized Enhancement and Analysis of Mammographic Findings") is pertinent in that it discloses a system where a radiologist reviews the findings of a CAD system.

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ryan J. Miller whose telephone number is (703) 306-4142. The examiner can normally be reached on M-F 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Leo Boudreau can be reached on (703) 305-4706. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9314.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 305-4750.

Ryan J. Miller
Examiner
Art Unit 2621

Ryan J. Miller
March 4, 2003

BRIAN WERNER
PATENT EXAMINER
ART UNIT 2621